SEAFOOD HACCP ENCORE COURSE

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INTRODUCTION

The Food and Drug Administration made significant changes to the rules regulating the safe and sanitary processing of fish and fishery products, including imported seafood, in December 1997 (the implementation date for the Seafood HACCP Regulation, 21 CFR 123). The regulations mandate the application of Hazard Analysis Critical Control Point (HACCP) principles to the processing of seafood. Since the implementation date, many processors have successfully developed and implemented HACCP programs to control food safety hazards associated with their products and processes. Additionally, many processors have developed and implemented successful sanitation monitoring programs, for the eight sanitation elements, that are required as part of the new regulation. While many have been successful in complying with the requirements of the regulation (both HACCP and sanitation monitoring), there remains a large segment of the industry for which compliance has been difficult. The Encore HACCP Training Program is designed to assist those processors who are experiencing difficulty in complying with the regulation. Moreover, it is intended to give regulatory personnel a more thorough understanding of HACCP to assist them in evaluating the adequacy of industry developed HACCP plans.

The National Seafood HACCP Alliance

The Seafood HACCP Alliance was founded through a project funded by the National Sea Grant College Program to develop a standard training and education program to assist the commercial and regulatory implementation of FDA's mandatory seafood HACCP inspection program. The Seafood HACCP Alliance Steering Committee includes representatives from three federal programs (FDA, USDA's Cooperative State Research, Education and Extension Service, and the National Marine Fisheries Service), state regulatory agencies through the Association of Food and Drug Officials (AFDO), the Interstate Shellfish Sanitation Conference, industry trade associations (National Fisheries Institute and the National Food Processors Association), and university faculty from extension and Sea Grant programs. Current funding for the Alliance is being shared by the National Sea Grant College Program, AFDO, and FDA.

Examples of Current Problems

Since implementation of the new regulation in December 1997, FDA has issued "untitled letters" and "warning letters" to processors citing deficiencies in their HACCP

plan and/or the sanitation monitoring program. Problems typically include:

- When a corrective action is listed in the HACCP plan, it often does not meet the requirements of 21 CFR 123.7(b), because it either: 1) does not adequately ensure that adulterated product does not enter the market; or 2) does not correct the cause of the deviation. For example, sensory analysis is not a suitable corrective action when time/temperature critical limits have been breached in the control of histamine. On the other hand, adjusting the cooler temperature in such a situation does not address the safety of the product exposed to the adverse condition.

- The distinction between which hazards must be addressed by the primary processor only (e.g., ciguatera, pesticides, aquaculture drugs) and those which must be addressed by any processor (e.g., histamine, pathogens, food additives) is apparently not clear.

- Where time/temperature controls are necessary to prevent a food safety hazard (e.g., exposure time during processing, cooler temperature, or presence of ice to prevent pathogen growth or histamine formation), the controls must be included in the HACCP plan, rather than controlled through application of GMPs or an SSOP.

- The linkage between the critical limit and the monitoring procedures is often weak. For example, monitoring cooler temperature is not an appropriate means of ensuring that a cooked product is cooled to the prescribed internal product temperature within the prescribed time period (i.e., critical limits), unless a study has been performed to relate the two under the least favorable processing conditions that are likely to occur.

- Setting a critical limit for maximum cooler temperature in which product is consistently stored iced has created a number of problems. Because the product is iced, processors often will not take a corrective action. However, this results in them deviating from their prescribed corrective action plans. A more appropriate scenario would be to prescribe corrective action only when: 1) the cooler temperature exceeds the limit and the product is not adequately iced; or, 2) the cooler temperature exceeds the limit and the product temperature exceeds a second limit.

- There must be scientific support for all critical limits selected by a processor (e.g., the time and temperature of a cooking process, the length of exposure of a temperature-sensitive product), and the support must be relevant to the processing conditions present in the facility. One source of support is FDA's Hazards and Controls Guide (subsequently referred to as the Guide).

The following table summarizes some of the common compliance issues documented in recent warning letters issued by FDA.

HACCP Compliance Issues

Summary of Common Compliance Problems
No written HACCP plan when one is needed Hazard not listed in plan Appropriate critical limits not listed Adequate monitoring procedures not listed Monitoring Procedures not followed Corrective action in plan not adequate Inadequate sanitation monitoring Inadequate sanitation monitoring records
Summary of Significant Hazards Not Listed In HACCP Plans
Ciguatera Histamine *Clostridium botulinum* toxin
Summary of Significant Hazards Not Adequately Controlled
Ciguatera Histamine *Clostridium botulinum* toxin Pathogens survival through cooking Sulfites

Course Agenda

Model Course Agenda

1 - Introduction and Background
2 - Module 1: Performing a Hazard Analysis for Fresh/Frozen Finish
- FDA video presentation on conducting a Hazard Analysis
- Practical: Hazard Analysis and Discussion

3 - Module 2: Performing a Hazard Analysis for Cooked RTE Crustaceans
- FDA video presentation on conducting a Hazard Analysis
- Practical: Hazard Analysis and Discussion

4 - Module 3: Performing a Hazard Analysis for Smoked Fish (optional)
- FDA video presentation on conducting a Hazard Analysis
- Practical: Hazard Analysis and Discussion

5 - Module 4: Developing a HACCP Plan for Fresh and Frozen Finfish
- FDA video presentation on developing a HACCP Plan
- Questions/Answers

6 - Module 5: Developing a HACCP Plan for Cooked RTE Crustaceans
- FDA video presentation on developing a HACCP Plan
- Questions/Answers

7 - Module 6: Developing a HACCP Plan for Smoked Fish (optional)
- FDA presentation on developing a HACCP Plan
- Questions/Answers

8 - Practical: Developing a HACCP Plan
- Participants (grouped in small teams) will develop a HACCP Plan. All groups can work on the same species and processes, or at the trainers discretion, chose different species and processes.
- Discussion of participant-developed HACCP Plans

9 - Module 7: Sanitation Monitoring
- FDA video presentation on sanitation monitoring
- Practical exercise and discussion

10. Course Wrap-up

Although a nationally consistent training course is important, relevance of the training to the participants is even more important. Consequently, a certain level of flexibility among training programs is expected. The opportunity for trainers to customize training to the needs of their audience is provided in two areas. First, it is expected that subsequent to the training videos and discussions, the trainer will break the participants into small groups (HACCP teams) and each team will then work on a Hazard Analysis and HACCP Plan for selected species/products. The species/products chosen is left to the preferences of the instructors and participants. The second area for added flexibility is the decision to include the Smoked Fish example into the training curriculum. The Alliance has included a smoked fish model as part of the Encore Training. However, in certain regions of the country where smoked fish processing does not exist, it may not be appropriate to include this product as part of the training. In its place, instructors have the option of including a model that is relevant to the needs of the audience, or expand the discussions on the previous

models (finfish or cooked ready-to-eat crustacean), or spend more time on the sanitation module. While the use of the smoked fish model is optional, the other components of the training are not. In order to assure training conformity the following agenda is recommended:

Understanding the Audience

In order to make the Encore Training meaningful, it is essential to know the issues that are of importance to the participants. Experienced instructors use various means to arrive at some level of understanding of their audience. One simple, but effective approach is to ask participants to introduce themselves and to tell everyone what types of products their companies produce. Obviously, this should be done at the very beginning of the course. This information is helpful in determining what issues need to be given emphasis as well as those that do not. For example, if no one processes smoked fish, the instructor may be wise not to use those modules in the course, and thus save time to focus on other areas. Also, if no one processes histamine-susceptible species then it may not be useful to dwell on issues associated with this hazard. Conversely, if processors of histamine-susceptible species are present, it would be prudent to assure that points relevant to this hazard receive emphasis. Finally, it is important to direct participants to additional sources of information or assistance available in the region (e.g., extension and sea grant specialist as well as FDA district offices).

Training Materials

A manual for the Encore course has been developed and is available from the Alliance Web Site at the University of California at Davis (http://www.seafood.ucdavis.edu/haccp/ha.htm) and through FDA's Web Site (http://www.fda.gov). Instructors may choose to download the manual and provide copies to the course participants, or notify participants of the web site's address and suggest that they download and print a hard copy to bring to the course. This manual will contain the text of the instructional videos, as well as the graphics and course introduction. For the practical exercises, it is recommended that instructors use material from the three-day Basic Seafood HACCP Course. Participants are expected to bring the following materials to the Encore Course:

- The Seafood HACCP Alliance Training Curriculum Manual (from three-day basic course)
- The FDA Fish and Fishery Products Hazards and Controls Guide
- Copy of the firm’s HACCP Plan (including process flow diagram, hazard analysis (if

available)[1]

- Copy of the firm's SSOP (if available)[1]

Models in Seafood HACCP Training Curriculum vs. Encore Course

Alliance training has traditionally underscored the dynamic nature of HACCP. Good examples of this are some differences in the expectations in the models provided in the Seafood HACCP Alliance Training Curriculum Manual and those discussed in FDA's video presentations. The models in the Curriculum Manual may be more rigorous than what FDA now considers reasonable to control certain hazards.

FDA's Hazards and Controls Guide

It should be noted that the Encore training relies heavily on the advice contained in FDA's Hazards and Controls Guide. This is intentional since the purpose of the training is to improve the level of compliance with the HACCP regulation, and the most direct way to assure compliance is to follow the guide.

The Guide contains FDA's best advice on those hazards that are reasonably likely to occur and the controls that are necessary to address them. The Guide contains a lot more information than can be provided in this short course format, so you should review it carefully on your own.

It is important that you understand that the material in the Guide is guidance only. It is not regulation. The Guide contains useful information on how to perform a hazard analysis and develop a HACCP plan. You can choose to perform your hazard analysis or control your hazards in a way that is different from what is outlined in the Guide, but understand that if you do, the burden is on you to demonstrate that you are providing an equivalent level of control.

To demonstrate an equivalent level of control may not be easy. It will always require some sort of scientific information - maybe a study, maybe a search of the literature. These efforts may be burdensome and, in most cases, it is unlikely that processors will choose to take on that burden.

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[1] These items could serve as the basis for discussion and examples if the participants are comfortable in sharing the information with the class.

This course is designed in part to make you familiar with the material contained in the Guide. Under most circumstances, if you follow that guidance you will have a HACCP plan that is acceptable to FDA.

Furthermore, some of the advice in the Guide is currently the subject of scientific discussion and debate. As these issues are resolved, changes in FDA recommendations may be reflected in subsequent editions of the Guide.

During the course, you may notice that a few shortcuts are taken from the process explained in the Guide. That was done to fit this material into the tight timeframes of a one-day course. But, you should use the formal HACCP process. It may save you from making some mistakes.

MODULE 1

PERFORMING A HAZARD ANALYSIS
PROCESSOR/DISTRIBUTOR OF FRESH/FROZEN FINFISH
(EXCLUDING SMOKED, COOKED, DRIED, SALTED, PICKLED, BREADED FISH)

This first module covers performing a hazard analysis for processors and distributors of raw, fresh and frozen finfish. It does not cover smoked, cooked, dried, salted, pickled, or breaded fish. Some of these products will be covered in later modules.

There are a few steps that should perform at the beginning of the hazard analysis. They will help you through the process of doing your hazard analysis. It may seem pointless to spend the time to develop this information, but often processors who skip this step, make mistakes later on in the hazard analysis.

You may use the checklist at the end of this module to keep this information together and as a quick reference.

- List all of the species of fresh or frozen finfish that you handle. Often processors of this type handle a long list of species.
- Identify those species which are purchased:
  - directly from the fisherman;
  - directly from the grower;
  - from another processor;
  - from a combination of these sources.
- Identify how the fish are received:
  - fresh - under refrigeration;
  - fresh - under ice or chemical refrigerant;
  - frozen;
  - more than one of these methods.

- Identify how the fish are stored after receipt:
  - fresh - under refrigeration;
  - fresh - under ice;
  - frozen;
  - more than one of these methods.
- Identify how the finished product will be shipped:
  - fresh - under refrigeration;
  - fresh - under ice or chemical refrigerant;
  - frozen;
  - more than one of these methods.
- Identify how the finished product will be packaged:
  - Traditional air-permeable packaging;
  - reduced oxygen packaging, such as: vacuum packaging, modified atmosphere packaging, controlled atmosphere packaging; hermetically sealed packages; or packed in oil.
- Identify those which are intended to be consumed:
  - raw;
  - cooked;
  - both raw and cooked.

If you put all this information on the checklist it could look like the completed example at the end of this module. One of the fish that this hypothetical firm handles is salmon. You can see that they receive both direct from the fishermen and direct from the grower. In both cases the fish are received fresh – refrigerated. They are stored fresh - refrigerated upon receipt, and the finished product is shipped both fresh - refrigerated and frozen. All products are packed in traditional air-permeable packaging and are intended to be cooked by the consumer.

Remember from your basic HACCP course, it is advisable to create a flow diagram for your product, where you identify each of the processing and storage steps. We are not going to cover that procedure here, except to say that you may find it useful to indicate next to each processing step on the flow diagram, the maximum length of time that the product could be exposed to unrefrigerated temperatures, and the maximum room air temperature, or, if you know it, the maximum internal product temperature, during that processing step. This will help you calculate maximum cumulative exposure time, something that's important for a variety of products. We will cover that in detail in a later module.

Species Related Hazards

This information, and the information in the checklist will help you perform the next two steps of the hazard analysis: brainstorming the potential hazards (i.e. hazard identification) and determining whether or not they are significant (i.e. hazard evaluation). Consider the list of hazards that might apply.

Natural Toxins

First is natural toxins. For finfish, these include: ciguatera, or CFP; amnesic shellfish poisoning, or ASP; and paralytic shellfish poisoning, or PSP. Although there are some differences, we'll cover them together. Ciguatera is a toxin that is associated with certain subtropical and tropical reef fish. ASP and PSP are toxins that are most commonly associated with molluscan shellfish, but can also be present in some finfish species.

To determine if the species you handle have a potential natural toxin hazard, you can look for a mark in the fourth column of (page 12) 3-1 in the Guide. These species have been associated with ciguatera toxin poisonings or with ASP or PSP levels above FDA's action level.

A natural toxin hazard is usually significant at the receiving step if all of these conditions are met:

- you received the fish directly from the fisherman; and
- there is an historical occurrence of the toxin in fish from any waters from which you receive fish; and
- in the case of ASP and PSP only, the fish are marketed uneviscerated. This last point is important, because toxic levels of ASP and PSP have not been found in the flesh of fish.

There is more on this subject in the Natural Toxins chapter of the Guide. Natural toxins in finfish is an example of a hazard that need only be controlled by the primary, or first, processor. Subsequent processors can rely on controls that are provided by the primary processor, and do not need to include controls for this hazard in their own HACCP plans.

Environmental Chemicals

Next, is the hazard of environmental chemicals (e.g. pesticides). Like you did with natural toxins, go to Table 3-1 in the Guide, but this time look in the sixth column. If there is a check there, this is a potential hazard. Finfish species listed this way are harvested from fresh water and near-shore locations.

The environmental chemicals hazard is usually significant at the receiving step if you receive the fish directly from the fisherman or grower, and either one of these conditions is also met:

- there are permanent or occasional closures to commercial harvesting of finfish in any harvest area from which you receive fish; or

- the fish are raised in ponds.

Environmental chemicals is another example of a hazard that need only be addressed by the primary processor. Secondary processors do not need to include controls for this hazard in their HACCP plans.

Aquaculture drugs

Next is aquaculture drugs. Again, go to Table 3-1, and look in column seven for a check mark. Or, you can just assume that if the fish is aquacultured, you will have a potential aquaculture drug hazard.

The aquaculture drug hazard is usually significant at the receiving step if you receive the fish directly from the grower - not if you receive it from another processor. In some regions and in some species (e.g. aquaculture of crayfish in the Gulf Coast region of the U.S.) aquaculture drugs are not used. In these cases, the hazard would not be significant. Aquaculture drugs is yet another example of a hazard that need only be controlled by the primary processor.

Parasites

The next hazard is parasites. This time look in Table 3-1 for a check mark in column 3. The marked species commonly contain infective parasites.

The parasite hazard is usually significant if the product is intended to be consumed raw. But, there are exceptions. The hazard would not usually be significant if:

- it is an aquacultured product that is raised on pelleted feed; or
- it was received already frozen; or
- you have obtained evidence that it will be frozen by a subsequent processor or institutional user.

Even so, there is considerable scientific debate about the frequency of occurrence of fishborne parasitic infections. FDA is in the process of collecting data on this subject, both in the U.S. and overseas. So, FDA will defer regulatory action for failure to control this hazard until after the data is collected and evaluated. This is a topic that you should continue to monitor. If, based on the data, FDA changes its position on the significance of the parasite hazard, the new position will be reflected in the next edition of the Guide.

Histamine

Histamine is a toxin that develops when certain species of finfish are exposed to time/temperature abuse. For this hazard, look in table 3-1 for a check mark in the fifth column. A check mark means that the species has a potential histamine hazard.

The histamine hazard is usually significant at the receiving step if:

- you receive fish directly from the fisherman; or
- if you receive the fish from another processor, unless the fish are received frozen.

The histamine hazard is also usually significant during processing or storage if unsafe levels of histamine could form as a result of cumulative time/temperature abuse. You may already have procedures in place in your plant that prevent this type of time/temperature abuse, such as: refrigeration, icing, or time/temperature management. To assess whether the histamine hazard is significant, you should consider the amount of time/temperature abuse that could occur if your existing procedures were not followed (e.g. if you did not use ice, refrigeration, or time/temperature management). If histamine could form under those conditions, then the hazard is significant.

There are exceptions. The hazard is not usually significant if the fish remains frozen during storage or processing. Also, it may not be significant for fresh fish products, during processing steps that are brief, such as mechanical filleting.

Recently, FDA updated the material in the Guide concerning histamine to provide information on the limits of safe exposure time/temperature. The new guidance limits are:

- for previously frozen fish:
  - 24 hours as long as the fish are not exposed to temperatures above 70^{o}F
  - 12 hours if the fish are exposed to temperatures above 70^{o}F.
- for fish that have not been frozen:
  - 8 hours as long as the fish are not exposed to temperatures above 70^{o}F
  - 4 hours if the fish are exposed to temperatures above 70^{o}F.

Remember, these are FDA recommendations. Other time/temperature combinations may also be valid if they can be shown to be scientifically supportable.

You apply the worst case unrefrigerated exposure times and temperatures you developed for each of the processing steps in the flow diagram for your product to these cumulative exposure limits. If the total is approaching the applicable safe exposure limit, you should usually consider the histamine hazard as significant for those processing steps. If not, the hazard is not likely to be significant.

That covers the significant hazards associated with the species of fish. But, as you know, hazards are not only species-related, but are also process-related. Now consider the process-related hazards that apply to fresh and frozen finfish.

Process-related Hazards

Table 3-3 (page 41) outlines the potential process-related hazards for different kinds of finished product. Most finished product categories are broken down by the packaging type – air pack or reduced oxygen pack. The reduced oxygen packaging categories are further broken down by the method of finished product storage – refrigerated or frozen. In the categories for raw fish, which includes both finfish and non-finfish species, four potential hazards are identified. Only three of those apply to raw finfish: pathogen growth as a result of time/temperature abuse; Clostridium botulinum toxin

formation; and metal fragments. The fourth, food and color additives, relates to the sulfite hazard in non-finfish species, which will be covered in the next module.

Clostridium botulinum

First is *Clostridium botulinum. C. botulinum* is a pathogen that grows in the absence of air and can produce a lethal toxin in the food. The table identifies *C. botulinum* as a potential hazard only for vacuum packaged, modified atmosphere packaged, and controlled atmosphere packaged fish, fish in hermetically sealed packages, and fish packed in oil - what are called reduced oxygen packaging.

The hazard is usually significant for fish in these packaging types unless the product is:

- packaged in an oxygen permeable package; or
- immediately frozen after processing, maintained frozen throughout distribution, and labeled to be held frozen and to be thawed under refrigeration immediately before use.

FDA is not currently aware of an effective control strategy for the *C. botulinum* hazard in fresh finfish in these packaging types, other than strict temperature control to ensure that the fish does not exceed 38^{o}F long enough to produce toxin. This strategy is not practical once the product leaves your control. There has been well-documented temperature abuse in the food-service, retail and consumer sectors, that makes reliance on temperature as the only means of control, under ordinary circumstances, unreasonable. However, processors may be able to develop control strategies (e.g. use of time/temperature integrators) that are effective in ensuring the control of *C. botulinum* toxin formation.

Pathogens

Growth of *Staphylococcus aureus* is also a concern in fresh finfish in these packaging types, because the reduced oxygen environment may give it a competitive advantage over the normal spoilage organisms. The formation of a heat stable toxin by this pathogen should also be considered in your hazard analysis of fresh fish in reduced oxygen packaging.

Metal

And the last hazard is metal fragments. This hazard is usually significant if worn, damaged, or broken equipment could contribute metal fragments to the product - for example, mechanical pickers or filleters, wire-mesh belts, saws, or mixing, blending, chopping, dispensing or portioning equipment. It is usually not significant if you have evidence that a control for metal fragments will be provided by a subsequent processor.

Species	Where Purchased			How Received			How Raw Material Stored			How Shipped			How packaged		How Consumed	
	Fisherman	Grower	Processor	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Air Pack	Reduced Oxygen	Raw	Cooked
Salmon	X	X		X			X			X		X	X			X

Species	Where Purchased			How Received			How Stored			How Shipped			How packaged		How Consumed	
	Fisherman	Grower	Processor	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Air Pack	Reduced Oxygen	Raw	Cooked

MODULE 2

PERFORMING A HAZARD ANALYSIS
PROCESSOR OF COOKED, READY-TO-EAT CRUSTACEAN
(INCLUDING CRAB, CRAYFISH, SHRIMP, LOBSTER)

This module continues the discussion of performing a hazard analysis. It covers a different product - cooked, ready-to-eat crustaceans. These include, cooked crab, crayfish, shrimp, and lobster.

Remember, there are some up front steps for the hazard analysis that were discussed in Module 1. They will not be covered again here. You can use the checklist that was also discussed in Module 1 as a quick reference.

Specie Related Hazards

Some of the hazards that were covered in the previous module, also apply to cooked, ready-to-eat crustaceans. As a result, the discussion for those hazards - in particular, ASP, PSP, and environmental contaminants (e.g. pesticides) - will be abbreviated here. The process you use to evaluate these hazards and to determine their significance in cooked crustaceans is the same as you used for finfish. The only difference is you use Table 3-2 (page 34), which covers invertebrate hazards.

<u>Aquaculture Drugs</u>

The next hazard is aquaculture drugs. Again, there are some similarities to finfish, but there is enough of a difference to cover it separately here. Look in column 7 of Table 3-2 for those species that have a potential aquaculture drug hazard.
Like finfish, the hazard is usually significant at the receiving step if you receive the fish directly from the grower - not if you receive it from another processor. Remember that there are some regions and some species in which aquaculture drugs are not used. If this is the case, there is no hazard.

However, unlike finfish, aquaculture drugs are also usually significant after receiving when lobster are being held in a pound. That is because, in some holding pounds drugs are used to combat animal diseases that can occur in intense culture.

Process Related Hazards

After you have determined the significant species-related hazards, you go again to Table 3-3 to determine the potential process-related hazards.

Sulfites

First is sulfites. Sulfites are a food additive, usually applied at harvest, that can cause a severe allergic reaction in sensitive individuals. This potential hazard exists for shrimp and lobster, and it is usually significant unless the product is grown or harvested in a region in which sulfites are not used.

Keep in mind that the sulfite hazard is not just significant for cooked shrimp and lobster. It can also be significant for raw shrimp and lobster.

Clostridium botulinum and Metal

The next two hazards are *C. botulinum* toxin formation and metal fragments. Again, the process you use for evaluating whether these hazards are significant for cooked crustaceans is the same as you used for finfish. That information will not be repeated here.

Pathogens

Because this product is intended to be consumed without further cooking by the consumer, there are a number of pathogen-related hazards. First is pathogen survival through cooking. The potential for this hazard exists for all products in the cooked, ready-to-eat category, and it will usually be significant unless you subsequently pasteurize or retort the product in the finished product container.

Two related hazards are pathogen survival through pasteurization and pathogen recontamination after pasteurization. The potential for these hazards exists for all pasteurized products, and is usually significant.

And finally, one of the more complex hazards to think through, is pathogen growth during processing. The potential for this hazard exists for all products in this category of cooked, ready-to-eat crustaceans.

To think through the significance of the hazard, start with receiving. Pathogen growth is usually significant at the receiving step if you receive cooked, ready-to-eat product from another processor. The exception is if the product is received frozen.

Next, consider processing and storage. The hazard is usually significant during

processing or storage of cooked, ready-to-eat products if, in the absence of controls (i.e. without refrigeration, icing, or time/temperature management) the cumulative time/temperature exposure could result in growth of pathogens to unsafe levels and/or toxin production. There are a number of things that affect your calculation of a safe time and temperature exposure. Primarily, we are concerned about the conditions that allow for growth of pathogens.

Table A-1 of the Guide (page 242) shows the ranges of growth for the pathogens most commonly associated with seafood. As you can see, factors like the amount of available moisture in the food (i.e. water activity), the amount of salt and preservatives, the acidity (i.e. pH), the temperature of the product, and the availability of oxygen all affect pathogen growth. But for these products, it is reasonable to assume that conditions will be favorable for pathogen growth when temperatures are between 40^{o}F and 140^{o}F.

Both time and temperature play a key role in pathogen growth. Table A-2 in the Guide (page 243) provides guidance about the kinds of time/temperature abuse that may cause a product to be unsafe. Keep in mind that pathogen growth is relatively slow at temperatures below 70^{o}F. In most cases it is very slow below 50^{o}F. On the other hand, growth is relatively fast at temperatures above 70^{o}F. So the Guide breaks up abuse temperatures into two main categories: 50^{o} to 70^{o}F; and 70^{o}F and above.

The overall recommendation is:

- no more than 4 hours of cumulative exposure, as long as no more than 2 of those hours are above 70^{o}F; or

- no more than six hours of cumulative exposure as long as the internal temperature never exceeds 70^{o}F; or

- if *S. aureus* is the only pathogen of concern, no more than three hours of cumulative exposure if the internal temperature at any time is above 70^{o}F; or

- if *S. aureus* is the only pathogen of concern, no more than 12 hours of cumulative exposure as long as the internal temperature never exceeds 70^{o}F.

FDA will be updating the guidance in the Guide in this area. Remember, though, that this information is guidance. Other time/temperature combination may also be valid if they are scientifically supportable.

An example of a situation in which *S. aurues* is the only pathogen of concern is the processing steps between cooking and pasteurization for pasteurized blue crabmeat. Remember, *S. aureus* produces a toxin that survives pasteurization. Most other

pathogens are eliminated by this pasteurization step.

You apply the worst case unrefrigerated exposure times and temperatures you developed for each of the processing steps in the flow diagram for your product to these cumulative exposure limits. As a general rule, if the total of the unrefrigerated exposure times for all of your steps after cooking is substantially less than two hours, you probably don't need to consider pathogen growth significant for those processing steps. If the total is approaching two hours, you will need to carefully consider the above limits. Most storage steps are longer than two hours, so this rule of thumb does not work well for them. You will need to consider them separately from the processing steps.

Remember, if control measures are needed to prevent the growth of pathogens, the hazard is significant and the controls must be included in your HACCP plan. It is not sufficient to rely on the application of GMPs or sanitation monitoring to address this hazard.

Pathogen growth is not usually significant during:

- periods of frozen storage; or,
- processing steps before the cook step; or
- cooling after cooking until the point that the product is first handled again; or,
- processing steps that are brief or mechanized - for example mechanical grading; or,
- processing steps prior to the pasteurization step, except that steps between the cook step and the pasteurization step may still be significant for the development of *S. aureus* toxin.

The Guide will be updated to reflect some of the changes in this material.

Species	Where Purchased			How Received			How Stored			How Shipped			How packaged		How Consumed	
	Fisherman	Grower	Processor	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Air Pack	Reduced Oxygen	Raw	Cooked

MODULE 3

PERFORMING A HAZARD ANALYSIS
PROCESSOR OF SMOKED FINFISH

The next product that will be covered is smoked finfish. Many of the potential and significant hazards are the same as those for fresh and frozen finfish that have already been covered, so the discussion here will be brief.

You can use the same checklist that you used for fresh and frozen finfish, and, again you will go to Tables 3-1 and 3-3 to identify the potential species and process related hazards.

Specie Related Hazards

All of the species-related hazards can be thought through the same way they were for fresh finfish, with two exceptions. First, since ASP and PSP are not significant in fish that are marketed eviscerated, and since all smoked finfish should be eviscerated before processing, you do not need to be concerned about this hazard in smoked finfish.

Second, the only additional point to keep in mind for histamine is that its development after hot smoking is not likely if further processing is performed using good sanitary practice. The heat destroys the bacteria that produce the histamine. There is also some question about the likelihood of histamine formation after the application of salt, and even more question about formation after the application of smoke. Further research is needed.

Process Related Hazards

Now consider the process-related hazards. Metal fragments can be thought through the same way as you did for fresh finfish. But the hazard of *C. botulinum* toxin formation should be thought through more carefully to determine if it is significant.

As with fresh fish and cooked, ready-to-eat crustaceans, the potential for the *C. botulinum* hazard exists for products that are vacuum packaged, modified atmosphere packaged, controlled atmosphere packaged, hermetically sealed, and packed in oil (i.e. reduced oxygen packaged products). But, the potential *C. botulinum* hazard also exists for hot-smoked fish, regardless of the packaging type. This is because: spoilage bacteria are reduced in number by the hot smoke; any surviving spoilage bacteria are less likely to grow because of the salt; and the spores of C. bot. are encouraged to grow by the lack of competing bacteria and the stimulation provided by the heat generated during smoking.

For smoked fish, the *C. botulinum* hazard is usually significant unless the product is:

- immediately frozen after processing; and
- maintained frozen throughout distribution; and
- labeled to be held frozen and to be thawed under refrigeration immediately before use.

The *C. botulinum* hazard is not usually significant in cold-smoked fish that is packaged in an oxygen permeable package.

Another process-related hazard that tends to get overlooked with smoked fish is the growth of pathogens other than *C. botulinum.* The potential for this hazard exists for all products in this category: with hot smoked fish because the heat has destroyed much of the competing spoilage bacteria; with both hot and cold smoked fish because the salt and smoke may inhibit the competing bacteria; and, with vacuum packaged smoked fish because the absence of air inhibits the remaining competing bacteria. Again, you can think through the significance of this hazard the same way you did for cooked crustaceans.

Species	Where Purchased			How Received			How Stored			How Shipped			How packaged		How Consumed	
	Fisherman	Grower	Processor	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Air Pack	Reduced Oxygen	Raw	Cooked

MODULE 4

DEVELOPING A HACCP PLAN
PROCESSOR/DISTRIBUTOR OF FRESH/FROZEN FINFISH
(EXCLUDING SMOKED, COOKED, DRIED, SALTED, PICKLED, BREADED FISH)

Now that you have done your hazard analysis, which includes hazard identification and hazard evaluation, the next step is to develop a HACCP plan. These next three chapters cover some of the more troublesome hazards and take you through development of a HACCP plan. Remember though, your HACCP plan would need to cover all significant hazards.

This module specifically covers fresh and frozen finfish, and the hazards that will be covered for developing a HACCP plan are: ciguatera; animal drugs; and histamine. This discussion does not represent any one specific species of finfish. It is for instructional purposes only that certain hazards have been selected and others omited that were discussed in the hazard analysis module. It is not likely that any one species of fish would have all of these hazards.

The discussion will be centered around the HACCP plan form that is provided in the Guide. The HACCP plan will be built one step at a time. You may notice that the form has been modified slightly in order to speed the presentation of the material. You should still use the form as it is presented in the Guide.

Ciguatera

Critical Control Point

The first hazard to be covered is ciguatera. For ciguatera, the CCP is usually the receiving step.

Critical Limit

An appropriate critical limits for ciguatera control is:

- No fish should be accepted from an area that is closed to commercial harvesting, or that is subject to a ciguatera advisory, or that is linked to a current ciguatera problem that you are aware of.

Monitoring

Since the critical limit for the ciguatera hazard is tied to the harvest area, monitoring should consist of obtaining the harvest area location from the fisherman for every lot of incoming fish.

Corrective Action

Predetermining corrective action is not required. But, if you do, the corrective action must be adequate. For the control of ciguatera, incoming lots that do not meet the critical limit should be rejected. In other words, if the product has been harvested from an implicated area, or if the source of the product cannot be determined, the product should be rejected.

Records

The monitoring record should document the harvest area location of every lot. Records of any corrective actions are also needed.

Verification

For verification purposes, a review of monitoring and corrective action records within one week of preparation is all that is needed.

Aquaculture Drugs

Critical Control Point

The next hazard is aquaculture drugs. The CCP for aquacultured drugs is usually the receiving step. Although, in some cases, it may be possible for you to control the hazard before the fish is harvested, for example in an vertically integrated aquaculture/processing operation.

Certain types of aquaculture drugs may be used, but only if they have been sanctioned by FDA. Sanctioning can take a number of different forms, and that can be somewhat complex. The Aquaculture Drugs chapter of the Guide provides a lot of information on that subject.

Critical Limits

You can set up your critical limits so that they allow only for the use of those drugs that are sanctioned. To do this you will need to either:

- monitor drug use before the fish are harvested; or
- look at your supplier's drug usage records at receipt.

Or, you can set your critical limits at the allowable residue for the drugs that might be used on your fish. To do this you'll need to either:

- test your incoming raw materials; or
- require that each shipment be accompanied by a supplier's or third party certificate attesting to proper use of aquaculture drugs.

Monitoring

There are several ways to monitor for aquaculture drug control. You can:

- perform an annual on-site audit of each growing site for drug use practices there. The audit should be designed to determine:
    - whether drug use records are maintained; and
    - that the records show that only sanctioned drugs are used; and
    - that sanctioned drugs are used in an appropriate manner; or
- examine your supplier's drug usage records at the time that you receive the lot; or
- test every lot of fish for residues of those drugs that may be present. A significant problem with this approach is that drug screening tests are not available for all drugs that might be used on fish and many that are available have not been fully validated. So, this approach will only be useful if appropriate tests are available, and, even then, you may need to validate the accuracy of the tests; or
- obtain a supplier's or third party certificate for every lot of raw material. Since supplier's certification is a relatively weak monitoring strategy, it must be coupled with strong verification procedures to be acceptable.

Corrective Action

Corrective action procedures are relatively simple. Lots that do not meet the critical limits should be rejected. In many cases it would also be prudent to discontinue use of the supplier until the cause of the noncompliance is identified and corrected.

Records

Depending on the control approach you are using, monitoring records can consist of:

- the results of on-site audits; or
- copies of your supplier's drug usage records; or
- analytical results; or
- copies of certificates coupled with records identifying the lots received.

Records of any corrective actions taken and records of verification activities that are part of the HACCP plan are also needed.

Verification

Finally, you should establish verification procedures. At a minimum, monitoring and corrective action records should be reviewed within one week of their preparation. And, when you are relying on supplier's certification, you should include a strong verification procedure, such as:

- periodic on-site review of the drug use practices of your suppliers; or
- quarterly drug residue testing for the drugs that may be used on your fish.

Histamine

The third and final hazard that will be covered in this module for fresh and frozen finfish is histamine. HACCP plan controls for histamine are complex, so they will be broken into four groups. The first two deal with control at receipt by the primary processor. One of these strategies relies mostly on harvest vessel records that show how the fish were handled onboard. The other relies mostly on histamine testing. The third strategy is for control at receipt by a secondary processor, which could be a warehouse. And the last strategy is control of histamine during processing, which applies to both primary and secondary processors.

Critical Control Point - Harvest Vessel Records Strategy

First consider control of histamine using harvest vessel records.
With this strategy, the CCP is receiving.

Critical Limits

The first critical limit addresses how quickly the fish are cooled on board the harvest vessel. Suitable critical limits include:

- For fish other than tuna and for tuna that are 20 pounds or less, as long as the fish have not been exposed to temperatures above 83°F: place the fish in seawater or brine that is at 50°F or less within 9 hours of death, or place the fish in ice within 12 hours of death; or

- For tuna above 20 pounds and for any fish exposed to temperatures above 83°F: reduce the internal temperature of the fish to 50°F or less within 6 hours of death.

Unless, the fish are then frozen, a critical limit should also be established to continue cooling onboard the harvest vessel to 40°F and to maintain the fish at or below 40°F until delivery.

In addition to critical limits for harvesting, critical limits should also be set for receiving by the processor. These critical limits should address decomposition and the internal temperature of the fish. They should include:

- No more than 2.5% decomposition in a sample of a lot of fish at receipt; and

- Unfrozen fish that are delivered between 12 and 24 hours after death should have an internal temperature of 50°F or below; or

- Unfrozen fish that are delivered 24 or more hours after death should have an internal temperature of 40°F or below.

Remember, these critical limits are FDA guidance. Other limits may also be valid if they are scientifically supportable.

Monitoring

You should obtain and review records from the harvest vessel for every lot of raw material. The harvest vessel records should contain enough data to enable you to determine whether the critical limits that you have chosen are met. Examples of the

types of data that are necessary, depending on the selected critical limits are:

- the method of capture;
- the time of landing;
- the estimated time of death;
- the method of cooling;
- the time cooling began;
- the air and water temperature;
- the cooling rate of the fish. The cooling rate can be measured by checking the internal temperature of the fish or by checking other factors, like brine temperature, that have been correlated to the cooling rate of the fish.

If unfrozen fish are held on the harvest vessel, the vessel records should also indicate:

- the temperature of the refrigerated seawater or brine; or
- that the fish were surrounded by ice over the course of the voyage.

You should also perform some monitoring at receipt. This monitoring should include:

- sensory examination to determine the amount of decomposition in the lot. FDA recommends that you examine at least 118 fish in each lot, or the entire lot it contains less than 118 fish. That means that a lot would fail your critical limit if three fish of the 118 fish (2.5%) are decomposed; and
- for unfrozen fish, determine the internal temperature of the fish at receipt.

Corrective Action

You will need to take corrective action whenever you fail to meet any critical limit. A critical limit failure could be:

- the absence of harvest vessel records; or
- inadequate cooling on board the harvest vessel; or
- high temperature at receipt; or

- excessive decomposition.

An appropriate corrective action for failure of any of these critical limits is to either:

- reject the lot; or

- perform histamine analysis. For failing to meet a critical limit during harvest, FDA recommends analyzing at least 60 fish in the lot, or the entire lot if it contains less than 60 fish, rejecting the lot if any fish is over 50 ppm. For failure to meet the sensory critical limit, FDA recommends testing all of the fish that show decomposition, again rejecting the lot if any fish is over 50 ppm.

Records

The recordkeeping system should include:

- harvest vessel records that contain the information described above, and

- results of the sensory examination; and

- for unfrozen fish, records showing the internal temperature of the fish.

Records of any corrective actions taken and records of verification activities that are part of the HACCP plan are also needed. In this case, verification records would include records of thermometer calibration.

Verification

Verification procedures should include:

- a review of monitoring and corrective action records within one week of their preparation; and

- calibration of thermometers, and

- quarterly histamine testing. This is recommended because of the heavy reliance on records supplied by the harvest vessel in this strategy. That kind of reliance compels you to have a strong verification procedure.

Critical Control Point - Histamine Testing Strategy

The second strategy for control of the histamine hazard replaces harvest vessel records, for onboard control of temperature, with histamine testing at the receiving CCP.

Critical Limits

The critical limits are the same as those for the harvest vessel control strategy, except that the critical limits relating to the harvest vessel records are replaced by a critical limit of less than 50 ppm histamine in the fish.

Monitoring

The monitoring procedures are also the same, except that those relating to harvest vessel records are replaced by histamine analysis of a sample of fish from every lot. FDA recommends that for fish that are 20 pounds or more, one fish per ton should be analyzed. For fish less than 20 pounds each, two fish per ton should be analyzed. The sample size can be reduced if the critical limit for histamine is reduced or if there is a substantial history of a low incidence of fish over the critical limit from a stable group of suppliers.

Corrective Action

Again, you will need to take corrective action when you fail to meet any critical limit. A critical limit failure could be:

- high histamine level; or
- high temperature at receipt; or
- excessive decomposition.

An appropriate corrective action for failure of any of these critical limits is to either:

- reject the lot; or
- perform intensive histamine analysis. For failure to meet the histamine critical limit, FDA recommends subdividing the lot and testing at the same rate, rejecting the sublot in which any one fish is over 50 ppm.

Records

The records required are the same as those for the harvest vessel control strategy, except that the harvest vessel records are replaced by histamine analytical results.

Verification

Finally, verification procedures should include:

- a review of monitoring and corrective action records; and
- calibration of thermometers.

Critical Control Point - Temperature Control During Transportation Strategy

The third strategy involves receipt by a secondary processor. Here, the histamine hazard is controlled by controlling temperatures during transport. Again, the CCP is receiving.

Critical Limits

For critical limits, either:

- there should be adequate ice or coolant at the time of delivery; or
- the shipment should be accompanied by transportation records showing that the fish were held at 40^{o}F or below throughout transport.

Monitoring

For monitoring procedures, either:

- visually check on the adequacy of ice or chemical coolant at receipt, for every shipment; or
- obtain some form of continuous temperature monitoring throughout transit, for every shipment.

Corrective Action

A suitable corrective action for any of these critical limits is to:

- reject the lot; or
- hold the lot until the total time/temperature exposure can be determined and evaluated; or
- test the lot for histamine. FDA recommends analyzing 60 fish, or the entire lot if it contains less than 60 fish, and rejecting it if any fish is over 50 ppm.

Records

Records should include:

- the results of the ice or coolant checks; or
- in-transit continuous temperature records.

Corrective actions and verification records are also necessary.

Verification

Verification procedures should include:

- record review; and
- calibration.

Critical Control Point - Temperature Control during Processing Strategy

The fourth and last strategy for control of the histamine hazard is control of time/temperature abuse during processing. This strategy relates to both primary and secondary processors. Your critical control points are those processing and storage steps at which you identified the hazard as significant.

Critical Limits

The critical limits are the same as the safe exposure limits that we discussed earlier in the hazard analysis module. They are:

- for previously frozen fish:
    - 24 hours as long as the fish are not exposed to temperatures above 70^{o}F
    - 12 hours if the fish are exposed to temperatures above 70^{o}F.
- for fish that have not been frozen:
    - 8 hours as long as the fish are not exposed to temperatures above 70^{o}F
    - 4 hours if the fish are exposed to temperatures above 70^{o}F.

Remember, you don't need to apply these critical limits to steps where the product is frozen, or to brief processing steps.

Monitoring

Both the processing and storage steps may need to be monitored, but the way you monitor them may be different. Monitoring for time/temperature abuse during processing can be done by visually observing the length of exposure of the fish to unrefrigerated conditions during processing. FDA recommends that this be done every two hours of operation. In some cases, it will also be necessary to check the ambient air temperature. For refrigerated storage, monitoring can be accomplished by checking the temperature of the cooler units at a frequency that will ensure that the critical limits are not exceeded. This will vary depending on your limits. If the fish are held under ice, a better approach is to simply check the presence of ice twice a day. Whichever, option you choose, you must document the monitoring procedures in your HACCP plan.

Corrective Action

Corrective action for deviations from these critical limits requires that you address both the cause of the deviation and the possibility that the product produced under these conditions may be unsafe. To address the cause of the deviation, you can take one of a number of actions:

- add ice; or
- make repairs or adjustments to the cooler; or
- move product from a malfunctioning cooler to another cooler; or
- move product from the production floor to a cooler; or

- freeze the product; or
- modify the process to reduce the exposure time.

To address the possibility of unsafe product, you should either:

- destroy the product; or
- divert the product to a non-food use; or
- collect and analyze a representative sample for histamine, rejecting the product if any unit exceeds 50 ppm.

Records

For records, you will need:

- cooler temperature records; and/or
- the results of ice checks; and/or
- the results of time/temperature exposure checks.

You will also need corrective action and verification records.

Verification

Again, verification involves:

- record review; and
- calibration.

MODULE 5

DEVELOPING A HACCP PLAN
PROCESSOR OF COOKED, READY-TO-EAT CRUSTACEAN
(INCLUDING CRAB, CRAYFISH, SHRIMP, LOBSTER)

This module covers cooked crustaceans, and the hazards that will be discussed for developing a HACCP plan are: sulfites; pathogen survival during cooking; and pathogen growth. Remember, though, your HACCP plan would need to cover all significant hazards. Again, the modified version of the HACCP plan form that is in the Guide will be used.

Sulfites

Critical Control Point

The first hazard to consider is sulfites. Where you set the critical control point will depend on the strategy you select for controlling the hazard. There are three possible strategies:

- labeling all products with a sulfite declaration;
- labeling only when sulfites are present in the raw material;
- receiving only raw material that does not contain sulfites so that the product does not need to be labeled.

If you decide to label all products with a sulfite declaration, or label when it is present in the raw material, the CCP will be at labeling or at label receiving. If you decide that you will not declare the presence of sulfites, the CCP will be at raw material receiving.

Critical Limits

Next, set the critical limits. If your CCP is at the labeling or label receiving step, your critical limit should state that:

- all labels must declare the presence of sulfites; or
- all labels must declare the presence of sulfites when they are present in the raw material.

If your CCP is at receiving, the critical limit will be:

- no detectable sulfites in the raw material; or
- a lot-by-lot certificate stating that no sulfites were used.

Monitoring

Monitoring is relatively easy. If your CCP is at the labeling or label receiving step, you should examine the labels to make sure they declare sulfite. FDA recommends that you look at one label from each case of labels or one label from each pallet of preprinted packaging material. If you will only declare the presence of sulfites when you determine they are present in the raw material, you should not only check the labels, but also representatively sample each lot of raw material and analyze it for sulfites. If your CCP is at receiving, you need only sample the raw material or obtain a lot-by-lot certificate.

Corrective Action

The appropriate corrective action for failing to properly label a lot is to:

- segregate and relabel the lot; and
- segregate and return or destroy any improper labels.

If your strategy is to not label product with a sulfite declaration, all raw material lots that contain detectable sulfites or that are not accompanied by a supplier's certificate should be rejected.

Records

Monitoring records should include:

- results of labeling checks; and/or
- copies of lot-by-lot supplier's certificates; and/or
- analytical results.

Corrective action and verification records are also necessary.

Verification

At a minimum verification procedures should include record review. If supplier's certificates are used, verification should also include:

- analysis of raw material from every new supplier; and
- at least quarterly analysis of randomly selected raw material for sulfite content.

Pathogen Survival through Cooking

Critical Control Point

You have already determined that pathogen survival during cooking is a significant hazard in cooked crustaceans. It is straight forward that the hazard will be controlled at the cook step.

Critical Limits

Critical limits for the cook step must be established by a scientific study that is designed to determine the time and temperature needed to destroy the targeted pathogen. The study need not be one that was performed specifically for your firm, but it must be applicable to your product and process. The critical limits usually include the length of the cook cycle and the cooking temperature.

Monitoring

Continuous time/temperature monitoring of the cook is necessary, with one exception. For boiling, visual observation of the length of the cook may be suitable. If the study identifies other factors that are critical to the cook, such as initial temperature, they should also be monitored as necessary. If the cooking operation is continuous, you must also monitor the length of the cook. One way to do that is to monitor the belt speed. You may be able to use another method of monitoring the cook step, if you can demonstrate its effectiveness.

Corrective Action

To address the cause of a deviation, you can take one of a number of corrective actions:

- adjust the processing temperature; or
- extend the length of the cook cycle; or
- adjust the belt speed.

To address the possible unsafe product, you should:

- destroy the product; or
- reprocess the product; or
- segregate and hold the product for a scientific evaluation; or
- divert the product to a non-food use.

Records

Monitoring records should include:

- recorder thermometer charts; and/or
- cooking logs that indicate the start and end of cook cycles; and/or
- the results of continuous cooking equipment timing checks.

You should also have corrective action and verification records.

Verification

Verification should include:

- record review; and
- calibration of thermometers; and
- studies or information that scientifically establish the adequacy of your cooking process and of the ability of your equipment to deliver the process.

Pathogen Growth

Critical Control Point

The last hazard that will be discussed for cooked, ready-to-eat crustaceans is pathogen growth. Like the histamine hazard, it is complex.

For the pathogen growth hazard, it's likely that wherever you identified the hazard as significant, those steps will be your CCPs. The CCPs will most likely be at:

- receiving, where refrigerated, cooked, ready-to-eat products are received from another processor; and

- processing and storage steps after cooking, where there is potential for significant time/temperature abuse of the cooked, ready-to-eat product.

Critical Limits

For receiving a cooked, ready-to-eat product from another processor, appropriate critical limits are either:

- adequate ice or coolant at the time of delivery; or

- the shipment must be accompanied by transportation records that show that the product was held at 40^{o}F or below throughout shipment.

The Guide will be modified to include some changes in the preceding recommendations.

Following is some information that relates establishing critical limits at CCPs at processing and storage. The hazard analysis module for cooked crustaceans contains FDA recommendations for safe exposure times and temperatures (i.e. exposure to temperatures between 40^{o}F and 140^{o}F. The safe exposure recommendations can be your critical limits. They are:

- no more than 4 hours of cumulative exposure, as long as no more than 2 of those hours are above 70^{o}F; or

- no more than six hours of cumulative exposure as long as the internal temperature never exceeds 70^{o}F; or

- if *S. aureus* is the only pathogen of concern, no more than three hours of cumulative exposure if the internal temperature at any time is above 70^{o}F; or

- if *S. aureus* is the only pathogen of concern, no more than 12 hours of cumulative exposure as long as the internal temperature never exceeds 70^{o}F.

Remember, these critical limits are cumulative for all steps in your operation, including storage. Start the clock when the product first undergoes significant handling after cooking.

Here are two examples of how these critical limits might be applied. Temperature profiles of these examples are included at the end of this module.

The first processor produces cooked blue crabmeat. In this case, after cooking, the product is fully cooled in the same container in which it was cooked and it is not handled until it is fully cooled. The processor will start the clock for the time/temperature exposure critical limit when the product is first handled, when it is brought out of the cooler to be backed, picked, and packed. In this particular plant, the temperature of the product never goes above 70^{o}F during processing, so the firm has selected the six hour critical limit. The product may not be exposed to unrefrigerated conditions during backing, picking, and packing for more than six cumulative hours. The firm will need to monitor both exposure time and product temperature.

The second processor also produces cooked blue crabmeat. But this firm only partially cools the product before it is handled to remove the backs. It is then further cooled, and finally, picked and packed. This processor will also start the clock for the time/temperature exposure critical limit when the product is first handled, but this time it is when backing of the hot crabs begins. Since the product is above 70^{o}F when it is first handled, the processor has two choices for critical limits. He selects the four hour option. The product may not be exposed to unrefrigerated conditions during backing, cooling after backing, picking, and packing for more than four cumulative hours. No more than two of those hours may be above 70^{o}F. The firm will use the two hours above 70^{o}F for the period that includes backing and cooling after backing, ensuring that the product is cooled to 50^{o}F or below in this two hour period. They will use the remaining two hours during the period that includes picking and packing, ensuring that the product does not exceed 70^{o}F during that period. The firm will need to monitor both time and temperature.

Monitoring

Next is monitoring. If you are receiving cooked, ready-to-eat products from another processor, you can either:

- obtain some form of continuous temperature monitoring throughout transit; or

- visually check on the adequacy of ice or chemical coolant at receipt.

The simplest approach to monitoring during processing is to determine the length of time that product is exposed to unrefrigerated conditions, and, if it is relevant to the critical limit, check the ambient air temperature or the internal temperature of the product. FDA recommends that this be done every two hours of operation. In some cases it may be possible to just monitor room temperature or product internal temperature, and not time.

During storage steps, you can monitor the temperature of the cooler. Cooler temperatures should be checked often enough to ensure that the critical limit is not exceeded. A better approach, though, if the product is iced, is to simply monitor the adequacy of ice. Checking ice on the product twice a day is sufficient.

Corrective Action

An appropriate corrective action for deviations from the receiving critical limit is to:

- reject the shipment; or
- hold the shipment until you can determine and evaluate the total time/temperature exposure.

To address the cause of a deviation from a critical limit during processing or storage, you can take one of a number of corrective actions:

- add ice; or
- make repairs or adjustments to the cooler; or
- move product from a malfunctioning cooler to another cooler; or
- move product from the production floor to a cooler; or
- freeze the product; or
- modify the process to reduce the exposure time.

To address the possibility of unsafe product, you should:

- destroy the product; or
- divert the product to a non-food use; or
- hold the product until it can be evaluated based on the total time/temperature exposure; or
- recook the product, if there's no preformed toxin hazard.

Records

Monitoring records should include:

- the results of time and/or temperature checks; and/or
- the results of checks on the presence of ice or other coolant; and/or
- temperature recorder charts.

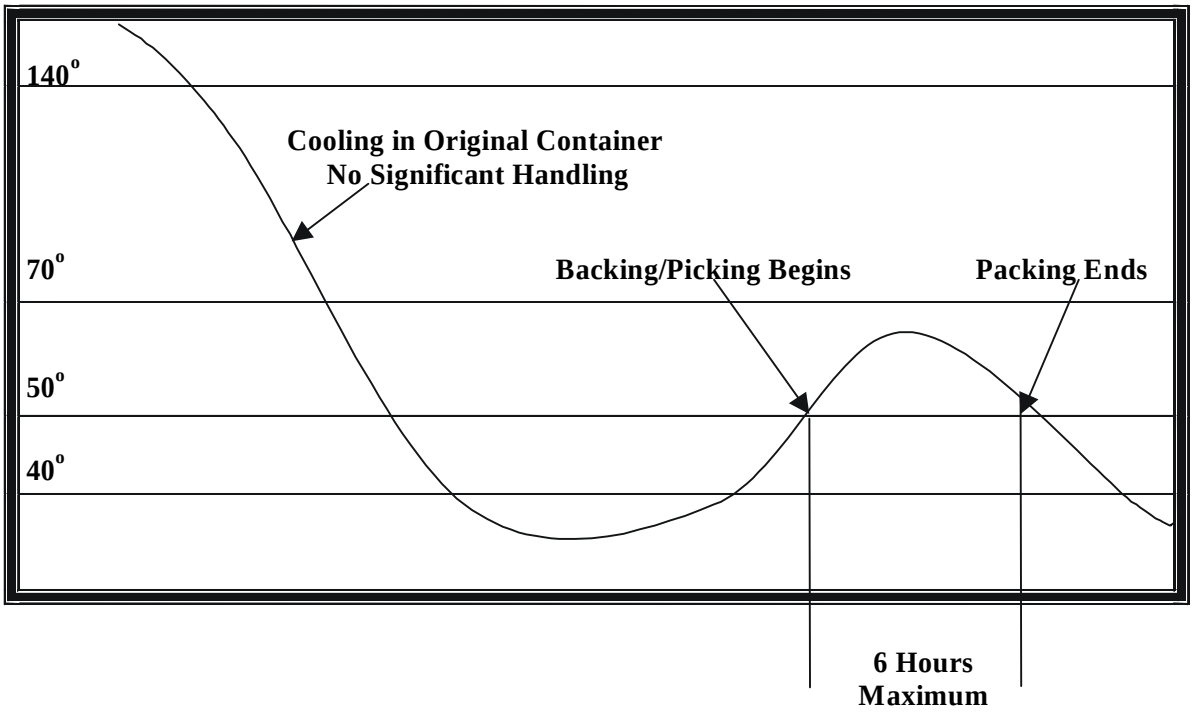
Verification

You will also need corrective action and verification records.

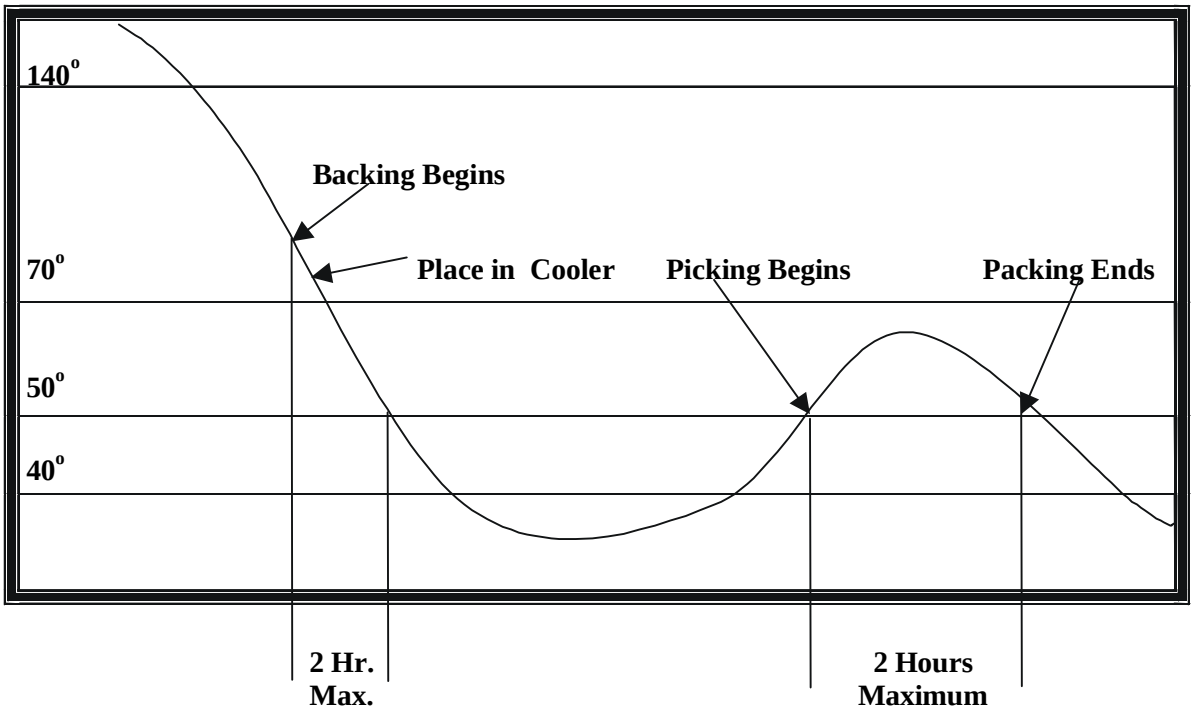
Verification should include:

- record review; and
- calibration of thermometers.

Internal Temperature Profile
Blue Crabmeat Processing
Cooling after Cook in Original Container with
No Significant Handling during Cooling



Internal Temperature Profile
Blue Crabmeat Processing
Partial Cooling Only after Cook
Significant Handling before Full Cooling



MODULE 6

DEVELOPING A HACCP PLAN
PROCESSOR OF SMOKED FINFISH

This module covers smoked finfish, and the hazard that will be discussed for developing a HACCP plan is *C. botulinum* toxin formation. But, remember, many of the other hazards that were discussed for the other products also apply to smoked finfish. As was stated earlier, one in particular that tends to get overlooked is the growth of pathogens other than *C. botulinum.* The same principles that were discussed for that hazard in cooked, ready-to-eat crustaceans apply to smoked finfish.

Critical Control Points

The control of *C. botulinum* toxin formation in smoked finfish requires controls at more than one processing step. The controls combine to create hurdles that minimize the risk of *C. botulinum* growth and toxin formation. It is the intricate combination of salt, smoke, temperature, and, sometimes, nitrite, that does the job.

Ordinarily, there are three reasons why a step could be identified as a CCP:

- control of water phase salt and nitrite levels;
- control of smoking temperature;
- control of time/temperature abuse during processing.

The brining or salting step and the drying step become the CCPs for control of water phase salt and nitrite levels. The smoking step is the CCP to control time/temperature during smoking. And, any other processing step should be identified as a CCP if there is a reasonable likelihood that time/temperature abuse significant enough to produce toxin could occur at that step. Most of the time, that is at processing steps after hot smoking, such as cooling. Since *C. botulinum* growth is not usually a significant hazard before reduced oxygen packaging in cold-smoked fish, steps before packaging will not ordinarily be identified as CCPs in that product, except, of course, the brining, salting, drying and smoking steps.

This module covers only the brining, salting, drying, and smoking CCPs. That is because if you are controlling for other pathogen growth during processing, those controls are adequate for *C. botulinum.* The controls for other pathogen growth have already been covered in a previous module. You should apply that information to this product.

Critical Limits

First consider the critical limits for the brining, salting and drying steps. These are the steps that affect the final water phase salt and nitrite levels, if nitrite is used. What you need to achieve is:

- a water phase salt level of at least 2.5% for air-packed smoked fish; or
- a water phase salt level of at least 3.5% for vacuum packaged or modified atmosphere packaged smoked fish; or
- a water phase salt level of at least 3% and a nitrite level of at least 100 ppm for vacuum packaged or modified atmosphere packaged smoked fish.

You can set your critical limits at those values, if you intend to test each batch of product. Or, you can conduct a study that lets you set limits for critical factors of the brining, salting, and drying operations that will reliably achieve those salt and nitrite levels. The critical factors are likely to include:

- brine strength; and/or
- brine to fish ratio; and/or
- brining time; and/or
- brine temperature; and/or
- drying time; and/or
- drier input or output air temperature.

Critical limits at the smoking step should be:

- for hot-smoked fish: an internal temperature throughout the fish of 145^{o}F or higher for at least 30 minutes;
- for cold-smoked fish: a maximum smoker temperature of 90^{o}F. It can be confusing, but for cold-smoked fish you actually have a maximum temperature limit. That is so you do not destroy the favorable acid-forming organisms that help keep the product safe.

Monitoring

There are two options for monitoring at brining, salting, and drying steps. They are:

- to determine the water phase salt, and, where appropriate, the nitrite level in a representative sample of each lot of finished product; or

- to monitor the critical factors of the brining, salting, and drying steps that were established by the study. Some factors, such as brine concentration and brine to fish ratio, only need to be monitored at the start of the process; others, such as brine temperature can be monitored periodically during the process (e.g. every two hours); and some, such as drier input or output air temperature should be monitored continuously.

For cold smoking, the temperature of the smoking chamber should be monitored continuously throughout the process. For hot smoking, the internal temperature at the thickest portion of three of the largest fish in the smoking chamber should be monitored continuously.

Corrective Action

Corrective actions to address the cause of a deviation from a brining, salting or drying critical limit, include:

- adjust the brine and/or nitrite concentration in the brine; or

- adjust the air velocity or input air temperature to the drying chamber; or

- extend the drying process; or

- adjust the brine to fish ratio; or

- extend the brining time.

To address the possibility of unsafe product, you can:

- destroy the product; or

- perform water phase salt analysis and, if necessary, nitrite analysis; or

- reprocess the product; or

- divert the product to a non-food use.

To address the cause of a deviation from a smoking critical limit, you can:

- make repairs or adjustments to the smoking chamber; or
- move some or all of the product to another smoking chamber.

To address the possibility of unsafe product, you can:

- destroy the product; or
- hold the product for a scientific safety evaluation; or
- divert the product to a non-food use; or
- for hot smoked fish, reprocess the product.

Records

Monitoring records include:

- analytical results; and/or
- brining, salting and drying records for critical factors identified by the study; and/or
- smoking time/temperature records.

Again, you will also need corrective action and verification records.

Verification

Finally, verification includes:

- record review; and
- thermometer calibration; and

- the following, unless your monitoring strategy involves analyzing every finished product lot for water phase salt:

  - scientifically establish the adequacy of your brining, salting, and drying operation to reliably deliver the desired water phase salt and nitrite levels; and

  - perform periodic finished product analysis for water phase salt, and, where appropriate, nitrite content. FDA recommends that you do this at least quarterly.

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Records	Verification
			What	How	Frequency	Who			

MODULE 7

SANITATION MONITORING AND CORRECTION

This final module outlines how to comply with the sanitation monitoring requirements of the Seafood HACCP regulation. Although sanitation monitoring requirements are new, sanitation standards have been in place for many years as part of FDA's Good Manufacturing Practice Regulation - 21 CFR Part 110 or the GMP's. There are many courses available that teach the basics of sanitation and how to comply with the GMP's. One such course will be available through the Seafood HACCP Alliance.

With the advent of HACCP, many have recognized that sanitation is a prerequisite to HACCP and provides a foundation for safe food production. In writing the Seafood HACCP regulation, FDA recognized that monitoring sanitation conditions would be necessary to achieve and maintain improvements in sanitation in fish processing operations.

The regulation requires monitoring in eight key areas of sanitation. Not all of these areas are relevant to all processing facilities. For example, many are not relevant to warehouses that store packaged fish. Monitoring is not required for those areas that are not relevant. These areas are somewhat arbitrary and overlapping, but were designed to include those aspects of the GMPs that are most likely to have an impact on the safety of the product. Your monitoring program may divide these issues differently. The eight key areas cited in the regulations are:

1. Safety of Water

This area relates to the source and treatment of water that comes in contact with food or food contact surfaces or is used in the manufacture of ice. It also relates to cross connections between potable and non-potable water systems. In seafood processing plants, cross connections are found in many places, such as: hard plumbing between potable and non-potable water lines; unprotected hose bibs (i.e. those with no backflow prevention devices); hoses lying in pooled water or submerged in wash tanks; or metering pumps used for cleaning chemicals without a backflow prevention device.

2. Condition and Cleanliness of Food Contact Surfaces

This area relates to the design, workmanship, materials, and maintenance of food contact surfaces and the routine, scheduled cleaning and sanitizing of those surfaces. It includes gloves and outer garments that may contact the food. Processing

equipment must be designed to be easily cleaned and maintained in a sanitary condition, and, it must withstand the environment of its intended use and the action of cleaners and sanitizers. This includes equipment for ice production and storage. At a minimum, cleaning and sanitizing of all equipment that contacts food should be done daily. All equipment should be cleaned at the end of each day's operation, and sanitized either after cleaning or before the day's operations begin.

If ready-to-eat products are being processed, cleaning and sanitizing should be accomplished more often. Intervals not to exceed four hours are recommended

Cleaning of all food contact surfaces is accomplished using detergent and water, whereas sanitizing is accomplished using compounds such as chlorine, quaternary ammonium or iodine.

3. Prevention of Cross Contamination

This area relates to: employee practices to prevent product contamination; physical separation of raw and cooked product; and plant design to prevent contamination.

Hands, gloves, outer garments, utensils, food contact surfaces of equipment that come in contact with waste, the floor, or other unsanitary objects can contribute to product contamination. Employees should be trained on how and when to properly wash and sanitize their hands, gloves and outer wear, as well as equipment, such as shovels and buckets, that come in contact with the floor or waste. It is also very important to stress that, in order to effectively clean equipment: all residual product must be removed; the equipment must be cleaned with hot water and detergent; and then the equipment must be sanitized.

Also covered in this area is the issue of cross contamination between raw and cooked products. The facility should either dedicate employees separately to work in either the raw or cooked side, or employees that move from the raw to the cooked product should wash and sanitize their hands, gloves and outer wear.

Unpackaged, cooked product must be separate from raw products during storage and processing to prevent cross contamination.

4. Maintenance of hand washing, hand sanitizing and toilet facilities

This area relates to the location and maintenance of hand washing, sanitizing and toilet facilities, as well as the adequacy of sewage disposal. Hand-washing facilities must be located in all processing areas where good sanitary practice requires employees to

wash their hands. Hand washing is necessary in a facility that produces raw fishery products to prevent the introduction of filth to the product. Hand washing and hand sanitizing is necessary for those employees that handle ready-to-eat food, or food packaging materials or food contact surfaces for ready-to-eat products to prevent the introduction of filth and pathogens to the product. Since hand-washing must come before hand sanitizing, hand washing stations must be located near dip stations. It is important that there is a supply of hot water and soap at each hand washing station and sanitizer at each hand sanitizing station. Toilet facilities must have adequate sanitary supplies and be in good repair.

5. Protection from adulterants

This area covers protection of food, food-packaging material and food contact surfaces from various microbiological, chemical and physical contaminants, such as lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate and floor splash.

6. Proper labeling, storage and use of toxic compounds

This area is covers labeling, storage and use of toxic compounds. It is important to note that improper use of toxic compounds is a frequent cause of product adulteration.

7. Control of Employee Health Conditions

This area relates to the exclusion of persons who appear to have an illness, wound or other affliction that could be a source of microbial contamination to the food. It is imperative that owners encourage employees not to work when they are ill or have an infectious wound that might contaminate the product.

8. Exclusion of Pests

This area relates to the presence of pests, such as rodents, birds, and insects. These pests carry a variety of human disease agents, which can be introduced into the processing environment. The presence of rodents, insects, birds or other pests in the processing plant is unacceptable. Even if pest control is contracted to an outside company, it is still your responsibility to make sure that there are no pests in the facility.

Sanitation Monitoring & Correction

Compliance with the sanitation monitoring requirements is twofold:

- observe and record the conditions in the plant; and
- take and record corrections for any deficiencies noted.

There are many ways to set up a sanitation monitoring program. Any number of them may be adequate for compliance with the regulation. One way is to place the sanitation elements into groups based on the frequency of monitoring. For example, decide which elements can be monitored monthly and daily. Then, prepare the monitoring records accordingly. Examples of blank and completed monthly and daily sanitation monitoring records are included at the end of this module. These example forms are only one way to record sanitation monitoring and may not apply to your situation. If you decide to split sanitation monitoring into daily and monthly monitoring, here is how it might look:

Monthly monitoring

Three areas that can be covered in a monthly monitoring report are **parts** of:

- safety of water; and
- condition and cleanliness of food contact surfaces; and
- prevention of cross contamination.

The conditions that are observed during monitoring are most commonly reported as "satisfactory/unsatisfactory, or "pass"/"fail."

1. Safety of water

How you monitor your water supply is dependent on the source of your water.

- Municipal source:

Frequency: Having a copy of the water bill attached to the monthly report would usually be sufficient. You could also request verification of the water quality from the municipal supply and maintain that record on file.

- Private source:

Frequency: Have the water tested for total coliforms on a semi-annual basis. The results of analysis should be maintained with the monthly report.

- Cross Connections: Monitoring of hard plumbing cross-connections between potable water lines and non-potable water and sewer lines.

Frequency: Once a month and more often if there are any changes to the plumbing.

2. Condition and Cleanliness of Food Contact Surfaces

- Monitoring the condition of processing equipment and utensils to assure compliance and determine if it is necessary to replace inadequate equipment.

Frequency: Once a month and more often if equipment is replaced or repaired to make sure that it meets the construction standards.

3. Prevention of Cross Contamination

- The monitoring requirement for proper plant design can be as simple as a monthly walk-through of your facility to assure that the plant layout and structure does not contribute to contamination of the product. Examples of the kinds of conditions that could contribute to contamination are:
    - Cooked product lines near raw product lines;
    - Excessively crowded processing conditions.

Frequency: Monthly. If any modifications are made to the facility, additional monitoring would need to be done to assure that the change did not contribute to the possibility of contamination.

Note: All observations must be reported at the time the observation is made.

Corrections

Critical to the success of the monthly monitoring record is the correction column. In this column corrections, that have been taken as a result of an observed deficiency, are recorded.

For example, if you receive a report of analysis for well water that shows high total coliform counts, your correction may be to stop processing and to resample immediately. If the resample is satisfactory, processing can begin. Another acceptable corrective action would be to find an alternative water source until the problem was corrected. All of this information is to recorded in the correction column.

Record identification

The monthly report must include: firm name; and location; date of record; and signature or initials of the person performing the monitoring.

Daily monitoring

The areas that can be covered in a daily monitoring report are **parts** of:

- safety of water; and
- condition and cleanliness of food contact surfaces; and
- prevention of cross contamination.

And all of:

- maintenance of hand-washing, hand-sanitizing, and toilet facilities;
- protection from adulterants;
- proper labeling, storage and use of toxic compounds;
- employee health conditions; and
- exclusion of pests

Note: just like the monthly monitoring records, daily monitoring records must reflect the actual conditions observed in the plant, as well as any corrections made as a result of

observed deficiencies.

1. Safety of water

- In addition to concerns about cross connections between hard plumbed potable water lines and nonpotable water and sewer lines, there is the possibility of other cross connections in the plant environment, such as: unprotected hose bibs with the hose submerged in the wash tank; or cleaning chemicals metering pumps.

Frequency: At least once during the course of the day. If all water lines, including all hose bibs, are protected with backflow prevention devices, daily monitoring may not be necessary.

2. Condition and cleanliness of food contact surfaces

- The portions of this area that should be monitored daily are: cleaning and sanitizing of equipment, utensils, gloves and outer garments that come in contact with food; and the condition of gloves and outer garments.

Frequency: Cleaning and sanitizing of all equipment should be monitored every time the equipment is cleaned and sanitized. That should include monitoring of sanitizer strength. The actual strength should be reported.

Note: The monitoring record can be set-up to cover each process area separately, or each process line separately, but it should cover the entire processing operation. For example, if there are two processing lines, one for raw finfish and the other for ready-to-eat fish, the raw finfish line may be monitored during the pre-op inspection only, while the ready-to-eat line should be monitored at that time and also every four hours thereafter.

Frequency: The condition and cleanliness of gloves and outer garments should be monitored at the start of the day's operations.

3. Prevention of cross contamination

- The issues in the area of cross contamination that should be monitored are: employee practices; and, physical separation of raw and cooked products.

Employee practices:

Frequency: Employee practices should be monitored at the beginning of the day's operation and at least every four hours during production, more often if necessary to ensure that employee's hands, gloves, equipment, and utensils are washed and sanitized, as necessary, after being contaminated. Monitoring employees that move from working in the raw side of the operation to the cooked side of the operation should be done at least every 4 hours during operations.

Separation of raw and cooked product:

Frequency: Coolers and processing areas should be monitored every four hours during operations and during the post-op inspection to ensure that unpackaged cooked product is separated from raw product.

4. Hand-washing, hand-sanitizing, and toilet facilities

- The fourth key area is the maintenance of hand washing, hand-sanitizing, and toilet facilities.

Hand-washing, hand-sanitizing facilities:

Frequency: The monitoring of hand-washing stations should be done during the pre-op inspection. The concentration of hand sanitizing solutions should be monitored during the pre-op inspection and every four hours during operation in the processing of ready-to-eat products.

Toilet facilities:

Frequency: The other part of this area is assurance that toilet facilities are adequate and in good repair. Seals around the bottom of each toilet, the functioning of the toilet, and toilet supplies should be monitored at least before the start of the day's operations.

5 & 6. Protection from adulterants/Labeling, storage and use of toxic compounds

- The fifth and sixth areas, "protection from adulterants," and "labeling, storage, and use of toxic compounds" can be combined in monitoring and reporting.

Protection from adulterants:

Frequency: Monitoring must be done to ensure that the food is protected from contaminants such as: condensate; floor splash; glass; and, toxic chemicals. These conditions should be monitored at start-up and every four hours thereafter.

Labeling and storage of toxic compounds:

Frequency: Once per day during the pre-op inspection.

7. Employee health conditions

- Employee health conditions must be monitored daily.

Frequency: Daily, before the start of production.

8. Pest control:

- Sanitation area eight is exclusion of pests.

Frequency: At a minimum, monitoring for pest should be done daily, during the pre-op inspection.

Corrections

As discussed with the monthly report, critical to the success of the daily report is the correction column, where corrections to observed deficiencies are recorded.

For example, if a check of the storage warehouse found rodent excreta pellets, the correction might be to remove the pellets and clean the area before start-up, and to call the pest control company to report the observation.

Record identification

The daily report must include: firm name; and location; and date of record; and signature or initials of the person performing the monitoring.

Sanitation Exercise

Based on what has been presented in the sanitation monitoring video, discuss and decide what is the best correction to the following sanitation deficiencies:

1. Line 2 (cooked ready-to-eat) is cleaned at the end of the day's processing, sanitized before use the next day, and then cleaned and sanitized at 4 hour intervals. During the 4 hour check, the sanitizer strength did not meet the required minimum.

2. Employees are trained to prevent cross-contamination by washing and sanitizing their hands, gloves, equipment or utensils when they may have become contaminated during the course of processing. Employee practices are monitored for this at the start of the day's processing and every 4 hours afterwards. During monitoring, an employee was observed to drop his fillet knife on the ground and then pick it up and continue to use it to make smoked salmon portions.

3. During a pre-op inspection of employees entering the processing area, one employee stopped to say that he didn't feel well, but was going to "tough it out" anyway.

DAILY SANITATION REPORT

Report Date: _____ **Firm Name:** _____
Firm Address: _____
_____

Line 1: Raw Seafood (not Ready-to-Eat)
Line 2: Ready-to-Eat

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments / Corrections
1) Safety of Water (See Monthly Sanitation Report)						
♦ Back Siphonage - Hoses (S/U)	☐					
2) Condition and cleanliness of food contact surfaces (See Monthly Sanitation Report)						
♦ Equipment cleaned and sanitized						
Line 1: (S/U)	☐					
Line 2: (S/U)	☐		☐	☐		
♦ Sanitizer Strength						
Sanitizer Type: _____ Minimum Strength: _____ppm						
Line 1: (ppm)	☐					
Line 2: (ppm)	☐		☐	☐		
♦ Gloves and aprons clean and in good repair						
Line 1: (S/U)		☐				
Line 2: (S/U)		☐				
3) Prevention of cross-contamination (See Monthly Sanitation Report)						
♦ Hands, gloves, equipment, and utensils washed / sanitized after contact with unsanitary objects (S/U)		☐	☐	☐		
♦ Employees working on raw products, wash and sanitize hands / gloves / outerwear before working with cooked products (S/U)			☐	☐		
♦ Unpackaged cooked products separated from raw products (S/U)			☐	☐	☐	

S = Satisfactory / U = Unsatisfactory

Sanitation Area and Goal	Pre-Op Time:	Start Time:	4 Hour Time:	8 Hour Time:	Post-Op Time:	Comments / Corrections
4) Maintenance of hand-washing, hand-sanitizing, and toilet facilities ♦ Hand-wash and hand-sanitizing stations adequate ▪ Hand-wash station Line 1: (S/U)	☐					
Line 2: (S/U)	☐					
▪ Hand-sanitizing station Sanitizer Type: _____ Minimum Strength: _____ppm Line 2: (ppm)	☐		☐	☐		
♦ Toilets clean, properly functioning, and adequately supplied (S/U)	☐					
5) Protection from adulterants and **6) Labeling, storage, and use of toxic compounds** ♦ Product protected from contamination (S/U)		☐	☐	☐		
♦ Cleaning compounds, lubricants, and pesticides labeled and stored properly (S/U)	☐					
7) Employee health conditions ♦ Employees do not show signs of medical problems (S/U)	☐					
8) Exclusion of Pests ♦ Pests excluded from processing area (S/U)	☐					

Additional Comments:

Signature (or Initials): _____

S = Satisfactory / U = Unsatisfactory

MONTHLY SANITATION REPORT

Report Date: _____ **Firm Name:** _____
Firm Address: _____
_____

Sanitation Area and Goal	Decision	Comments / Corrections
1) Safety of Water ♦ Safe and sanitary source (semi-annual) (S/U) ♦ No cross-contamination - Hard Plumbing (S/U)	☐ ☐	
2) Condition and cleanliness of food contact surfaces ♦ Processing equipment and utensils in suitable condition (S/U)	☐	
3) Prevention of cross-contamination ♦ Physical conditions of plant and layout of equipment (S/U)	☐	

Additional Comments:

Signature (or Initials): _____

S = Satisfactory / U = Unsatisfactory

Species	Where Purchased			How Received			How Stored			How Shipped			How packaged		How Consumed	
	Fisherman	Grower	Processor	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Refrigerated	Iced	Frozen	Air Pack	Reduced Oxygen	Raw	Cooked

Critical Control Point (CCP)	Significant Hazard(s)	Critical Limits for each Preventive Measure	Monitoring				Corrective Action(s)	Records	Verification
			What	How	Frequency	Who			